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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,506	05/25/2001	Ghita Lanzendorfer	BEIERSDORF70	8673

7590

09/18/2002

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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 09/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,506

Applicant(s)

LANZENDORFER ET AL.

Examiner

Lauren Q Wells

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 8-20 are pending. Claims 1-7 were cancelled per the Preliminary Amendment filed July 5, 2001.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on August 1, 1998. It is noted, however, that applicant has not filed a certified copy of the German application as required by 35 U.S.C. 119(b). While Examiner is aware that this Application is a 371, the Examiner respectfully notes that there is no photocopy of the certified foreign priority document and that it appears that a certified copy was not sent to the International Bureau.

Specification

The amendment filed January 24, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: claims 16-17. In the original disclosure, there is no mention of encapsulated forms.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 8-9, 13, 15, 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The term "derivatives" in claims 8, 13, 15, and 20 is vague and indefinite, as it is not clear what vast array of compounds is encompassed by this phrase.

(ii) Claim 9 is vague and indefinite, as it is not clear how auxiliaries, additives, and other active ingredients differ from each other. The specification does not bring differentiate between these three terms and one of ordinary skill in the art would not be apprised of the differences.

(iii) Claim 17 is vague and indefinite, as it is confusion. How can a form be made up of compounds/polymers? Is the claim referring to the compounds/polymers that comprise the capsule of the encapsulated form? Furthermore, what are collagen matrices, cellulose encapsulations, wax matrices, and liposomal encapsulations? What chemical structures are encompassed by these terms? The specification does not shed light on these terms and one of ordinary skill in the art would not be apprised of them.

(iv) The term "strengthening" in claims 19 and 20 (line 1) is a relative term which renders the claim indefinite. The term "strengthening" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(v) The phrase "barrier function" in claims 19 and 20 (line 1) is vague and indefinite, as it is not clear what the barrier function of the skin is. The specification does not define it and one of ordinary skill in the art would not be apprised of it.

(vi) Claim 18 is vague and indefinite. How can this claim depend from claim 16? How can the composition be in two forms at once?

(vii) Claim 15 is vague and indefinite. How can this claim depend from claim 8? Claim 8 limits the active agent to bile acids and salts and derivatives of these acids, yet claim 15 recites a variety of different active agents.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 8-9, 13, 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bolcsak et al. (5,100,662).

Bolcsak et al. teach steroid vesicles comprised of a derivatized sterol, wherein bile acids comprise the derivatized sterol. The vesicles are disclosed as liposomes. Taurocholic acid and desoxycholic acid are disclosed as exemplary bile acids. Auxiliaries, additives, and other active ingredients are disclosed. Solution forms are disclosed. See abstract; Col. 10, line 21-Col. 16, line 8; Col. 23, line 20-Col. 26, line 56.

Claims 8-11, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Sorbini (4,185,099).

Sorbini teaches a cosmetic composition comprising chenodeoxycholic acid or ursodeoxycholic acid. The acids are disclosed as comprising 0.6-1% of the composition. Auxiliaries, additives, and other active ingredients are disclosed. See Col. 1, line 40-Col. 4, line 45.

Claims 8-13, 15, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Mueller et al. (5,002,761).

Mueller et al. teach hair conditioner compositions comprising cholic acid salts, cholic acid, saponin taurocholic acid, and deoxycholic acids. These compounds are disclosed as comprising from 0.1-0.5% of the composition. Auxiliaries, additives, and other active ingredients are disclosed. See Col. 2, line 15-Col. 6, line 69.

Claims 8-9, 13, 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Pittrof et al. (5,747,066).

Pittrof et al. teach mixed micelles consisting of phosphatide and bile acid salt. Alkali salts of cholic acid, glycocholic acid, taurocholic acid, deoxycholic acid, glyco or taurodeoxycholic acid, chenodeoxycholic acid and glyco or taurochenoxydeoxycholic acid are disclosed as bile acid salts. It is disclosed that the mixed micelles can contain pharmaceutically active substances for parenteral, topical, including cosmetics, or oral administration. Auxiliaries, additives, and other active agents are disclosed. See Col. 1, line 60-Col. 4, line 60; Col. 7, line 39-Col. 10, line 53.

Claims 8-10, 13-15, 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Yoo (6,251,428).

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Yoo teaches compositions comprising water, bile acid in the form of bile acid, bile acid salt, or bile acid conjugated with an amine, and a water soluble starch conversion product. Bile acid derivatives disclosed include those formed at the hydroxyl and carboxylic acid groups of the bile acid with other functional groups. Specifically exemplified bile acids are ursodeoxycholic acid, chenodeoxycholic acid, cholic acid, deoxycholic acid, hyodeoxycholic acid, deoxycholic acid, lithocholic acid, tauroursodeoxycholic acid, and others.. The bile acids are disclosed as comprising more than 1.17% of the composition. Auxiliaries, additives, and other active ingredients are disclosed.

Claims 8-13, 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Sipos (5,750,104).

Sipos teaches gastric acid-resistant polymer coated buffered digestive enzymes/bile acid composition. Urodeoxycholic acid is disclosed as a bile acid. The bile acid is disclosed as comprising from 0 to 20% of the composition. The coatings are disclosed as being comprised of cellulose encapsulations. See Col. 3, line 1-Col. 18, line 65.

Claims 8-13, 15, 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Shinji (JP 03058918).

Shinji teaches a deodorizing composition containing a bile acid salt. The bile acid salt includes deoxycholic acid, alkali metal salt of cholic acid or both. The bile acid salt is disclosed as comprising 0.1-5% of the composition. Auxiliaries, additives, and other active agents are disclosed. The composition is disclosed as a solution. See abstract.

Claims 8-13 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahn (FR 2751534).

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Ahn et al. teach compositions comprising urso-desoxy cholic acid and/or cheno-desoxy cholic acid. The acids are disclosed as comprising 0.02-1% of the composition. Toothpastes, mouthwashes, chewing gums, and buccal massage creams are disclosed as forms of the composition. See abstract.

Claims 8-10, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Clauzure (FR 2551991).

Clauzure teaches stable aqueous emulsions of essential oils and/or liposoluble materials in a water or hydroalcoholic medium, wherein bile salts are the emulsifying agents in the composition. Cholic acid, glycocholic acid, taurocholic acid, and desocycholic acid are disclosed as bile salt acids and are further disclosed as comprising at least 2% of the composition. See abstract.

Claims 8-9, 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Pittrof et al. (EP 439042).

Pittrof et al. teach a pharmaceutical composition or cosmetic preparation for topical administration comprising a bile acid salt, a lipid, and a cosmetic active agent. Sodium glycocholate is disclosed as a preferred bile acid salt. The form of the composition is disclosed as a solution and as a micelle. The composition is disclosed as providing good penetration of the skin and good skin and eye tolerability. See abstract.

Claims 8-13, 15 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Caserio et al. (EP 0058000).

Caserio et al. teach cosmetic compositions comprising cholanic acid derivatives and powder absorbents. Water and other liquid carriers are disclosed as optional additives.

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Desoxycholic acid, glycocholic acid and taurocholic acid, and sodium desoxycholate are disclosed as cholic acid derivatives. The cholic acid derivatives are disclosed as comprising 0.1-20% of the composition. The composition is disclosed for removing sebum and/or perspiration. See entire disclosure.

Claims 8-13 and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10120579.

JP '579 teaches an external skin treatment for improving water balance in body fluid comprising 0.001-10% of a bile acid. Deoxycholic acid and taurocholic acid are disclosed as bile acids. See abstract.

Claims 8-9, 13, 15, 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by De Moragas et al. (DE 19522694).

De Moragas teaches cosmetic compositions containing phospholipid, bile acid, ethanol, and water. The composition is used as a bathing agent to treat skin diseases such as psoriasis or eczema. Desoxycholic acid, taurocholic acid, ursocholic acid and their salts are disclosed as bile acids. See abstract.

Claims 8-13, 15, 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 03058918.

JP '918 teaches a composition comprising bile acid salts. Alkali salts of deoxycholic and/or cholic acid are disclosed as bile acid salts. The salts are disclosed as comprising 0.5-3% of the composition. Alcohol is disclosed as a solvent. The composition is used for the controlled growth of Staphylococcus bacteria. See abstract.

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Claims 8, 10-12 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10120561.

JP '561 teach external dermal compositions containing hydroxy fatty acids and/or its salts, such as that of cholic acid. The acid is disclosed as comprising 0.001-10% of the composition. The composition is used for skin conditioning and treating skin disorders. See abstract.

Claims 8-15 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Lyon et al. (4,115,313).

Lyon et al. teach emulsions comprising bile acids, their conjugates, lower alcohol esters or salts of acids or conjugates; water; glycerides; phospholipids; fatty acids, amino fatty acids, or fatty acid amides; and steroids. Deoxycholic acid is disclosed. The bile acid salt is exemplified as comprising 0.125% of the composition. See Col. 2, line 7-Col. 7, line 25; Col. 9, line 65-Col. 12, line 13; Col. 21, line 60-Col. 22, line 66.

Prior Art

The prior art made of record and not specifically relied upon in any rejections cited above is either 1) considered cumulative to the prior art that was cited in a rejection or is 2) considered pertinent to the applicant's disclosure and shows the state of the art in its field but is not determined by the Examiner to read upon the invention currently being prosecuted in this application.

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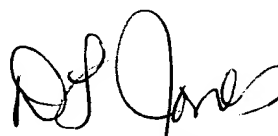
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
September 20, 2001


DAMERON L. JONES
PRIMARY EXAMINER